UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/621,027	07/16/2003	Nai-Kong V. Cheung	#639-B-PCT-US	2089

7590 01/04/2007

Law Offices of Albert Wai-Kit Chan, LLC
World Plaza, Suite 604
141-07 20th Avenue
Whitestone, NY 11357

EXAMINER	
OLSON, ERIC	
ART UNIT	PAPER NUMBER
1623	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/04/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/621,027	CHEUNG, NAI-KONG V.	
	Examiner	Art Unit	
	Eric S. Olson	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 September 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *149-192* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *149-192* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *16 July 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *See Continuation Sheet*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :5/16/05, 3/29/05, 11/24/04, 11/12/04, 9/27/04, 4/14/04.

Detailed Action

This office action is a response to applicant's arguments and amendment submitted September 7, 2006 wherein claims 149 and 155 are amended and new claims 189-192 are introduced. This application is a continuation-in-part of PCT/US02/01276, filed January 15, 2002, which claims benefit of provisional application 60/261911, filed January 16, 2001.

Claims 149-192 are pending in this application.

Claims 149-192 are examined on the merits herein.

Applicant's amendments submitted September 7, 2006 with respect to the rejection of instant claim 155 under 35 USC 112, second paragraph for being indefinite, has been considered and found persuasive to remove the rejection of these claims because claim 155 now clearly recites "an antibody" rather than "an antigen." Therefore the rejection is withdrawn.

The previous rejection of instant claims 149-160, 163-184, 186, and 188 under 35 USC 103 as being unpatentable over the combination of Herlyn, Jamas et al., Yan et al., Marciani et al., Cheever et al., Chu et al., and Lane et al., is withdrawn.

The following rejections made in the prior office action are maintained:

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 149-192 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods and compositions comprising a beta-glucan and one or more specific monoclonal antibodies for the treatment of specific cancers, does not reasonably provide enablement for methods and compositions comprising any antibody whatsoever for the treatment of any cancer whatsoever. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The Applicant's attention is drawn to *In re Wands*, 8 USPQ2d 1400 (CAFC1988) at 1404 where the court set forth eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:
(1) The nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

Nature of the invention: The claimed invention is drawn to compositions comprising an antibody and a glucan which are suitable for the treatment of cancer.

The state of the prior art: The prior art discloses various monoclonal antibody therapies against tumors. The prior art also discloses that beta-glucan produces an

anti-tumor effect *in vivo* by stimulating the immune system against a tumor, and can enhance the effects of both endogenous and exogenous antibodies. The current state of the art in antibody therapy is not such that a routine, predictable, and effective antibody therapy exists for each and every cancer which could possibly be encountered.

With regards to generalizing specific results to the treatment of all cancers, the skilled artisan would view cancer as a group of maladies not treatable with one medicament or therapeutic regimen. No single therapy is useful for the treatment of every case of cancer. Indeed, some types of cancer to not respond well to any known chemotherapeutic drugs. According to the Merck Manual of Diagnosis and Therapy (Reference included with PTO-892), Hepatocellular carcinomas and renal cell carcinomas are not generally improved by chemotherapy. Acute lymphoblastic leukemia, on the other hand, responds well to a number of drugs, including vincristine, anthracyclines, and aspariginases, while acute mylogenous leukemia, on the other hand, responds to fewer drugs and is usually treated with cytarabine in combination with daunorubicin or idarubicin. Breast cancer, on the other hand, is best treated with surgery and/or radiation, but the prognosis can be improved by the addition of adjuvant chemotherapy. While results for antibody-based therapies are less completely studied, there is no reason for one skilled in the art to expect that tumors will display less heterogeneity with respect to antibody therapy.

The relative skill of those in the art: The relative skill of those in the art is high.

The predictability or unpredictability of the art: As mentioned above, no single treatment is effective for all cancers. Different cancers vary widely in their response to

different chemotherapy regimens. According to the Oxford Textbook of Oncology, (Reference cited in PTO-892) "The important criteria for the tumor include its sensitivity to cytostatic drugs, its clinical stage and its mass, the presence of measurable lesions or biochemical markers, and, finally, growth characteristics," as well as, "*In vitro* sensitivity tests have been disappointing. They predict well for resistance but are of little use for sensitivity," (p. 451, right column, second paragraph) and, "For many types of cancer the potential benefit of chemotherapy has not been demonstrated in well-designed clinical trials."

Based on the known teachings of the prior art such as that stated above, one skilled in the art would recognize that it is highly unpredictable in regard to the treatment in the instant case, including treating numerous and various tumors: gynecological tumors, ovarian carcinomas, testicle tumors, prostate carcinomas, skin cancer, kidney cancer, bladder tumors, esophagus carcinomas, stomach cancer, rectal carcinomas, pancreas carcinomas, thyroid cancer, adrenal tumors, various types of leukemia and lymphomas, Hodgkin's disease, tumor illnesses of the CAN, soft-tissue sarcomas, bone sarcomas, benign and malignant mesotheliomas, especially intestine cancer, liver cancer, breast cancer, bronchial and lung carcinomas, melanomas, acute and chronic leukemias and benign papillomatosis tumors, by performing the necessary experimentation to develop an optimized dose-dense protocol for treating said cancers.

There are compounds that treat a range of cancers, but no one has ever been able to figure out how to get a compound to be effective against cancer generally, or even a majority of cancers. Thus, the existence of such a "silver bullet" is contrary to

our present understanding in oncology. The treatment of cancer is highly unpredictable due to the differing forms of cancerous cells, their location, their potential for metastases, the fact that cancer therapeutics are palliative rather than curative and that cancer treatment readily harms normal tissues (see Katzung pp. 881-882). Even the most broadly effective antitumor agents are only effective against a small fraction of the vast number of different cancers known. This is true in part because cancers arise from a wide variety of sources, such as viruses (e.g. EBV, HHV-8, and HTLV-1), exposure to chemicals such as tobacco tars, genetic disorders, ionizing radiation, and a wide variety of failures of the body's cell growth regulatory mechanisms. Different types of cancers affect different organs and have different methods of growth and harm to the body, and different vulnerabilities. Thus, it is beyond the skill of oncologists today to get an agent to be effective against cancers or tumor cells generally by enhancing the effectiveness of antibodies generally or the wherein the antibody is capable of activating complement or dependent cell-mediated cytotoxicity

Note that the pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. In re Fisher, 166 USPQ 18 indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute. Additionally, by Applicant's own admission, "Applicant's groundbreaking technology does not fit into the known paradigms of the cancer treatments [conventional chemotherapeutic treatments] to which Examiner refers." (Applicant's arguments dated September 12, 2006, p. 15, third paragraph) Applicant's methods do not involve known drugs for which comprehensive pharmacological data,

such as optimal dosages and effectiveness against specific cancers, is not yet available. The fact that a particular therapy is groundbreaking and outside of the conventional art-recognized paradigm weighs against its predictability. Extraordinary, paradigm-shattering claims require correspondingly extraordinary evidence.

The Breadth of the claims: The claimed methods and compositions include methods and compositions capable of treating any cancer whatsoever, regardless of cause, parent cell type, antigen expression, and therapeutic resistance.

The amount of direction or guidance presented: Applicant's specification discloses that exogenous antibodies can be rendered more effective against cancer by the co-administration of beta-glucan. However, Applicant's specification does not define the limits of this therapy or provide a reasonable basis by which one skilled in the art may conclude that it is generally applicable to all cancers.

The presence or absence of working examples: Working examples are provided for therapies against specific tumors using antibodies against specific targets. These examples are not sufficient to be representative of every possible tumor which could conceivably afflict a subject.

Note that lack of working examples is a critical factor to be considered, especially in a case involving an unpredictable and undeveloped art such as synergistic beta-glucan/antibody therapy. See MPEP 2164.

The quantity of experimentation necessary: : In order to use the disclosed information to practice the claimed invention for a wide range of cancers using a wide range of antibodies, a skilled practitioner of the art would develop a wide variety of

antibodies against a wide variety of targets. This would involve a process of optimizing and testing various regimens *in vivo* for each type of cancer being treated. Because the art is still undeveloped, this process would involve unpredictable experimentation which would constitute an undue experimental burden on the practitioner.

Genentech, 108 F.3d at 1366, sates that, "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion." And "patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable."

Therefore, in view of the Wands factors, as discussed above, particularly the unpredictability of the art and the lack of guidance and working examples, Applicants fail to provide information sufficient to practice the claimed invention for the treatment of all possible tumors.

Response to Argument:

Applicant's arguments, filed September 7, 2006, with respect to the previous rejection of claims 67-107 under 35 USC 112, first paragraph, for lacking enablement for treating all possible cancers, have been fully considered but not found persuasive to remove the rejection. Applicant argues that synergistic antibody-beta-glucan therapy is a sufficiently ground-breaking, exceptional therapy that it transcends the normal limitations suffered by conventional cancer therapy, and in fact by medicine in general. To substantiate these claims, Applicant points out the differences between this therapy and conventional cytotoxic chemotherapy, and the presence of a significant number of publications in this field reporting success against specific tumors, generally in mouse

xenograft models. However, these arguments and examples fail to provide the extraordinary proof needed to demonstrate that this therapy is indeed the claimed silver bullet against all cancers. As described above, cancer is a highly heterogeneous phenomenon which cannot be regarded as a single infectious agent to be eradicated by a single specific therapy. Furthermore, like bacteria and viruses, cancer is a highly adaptive phenomenon capable of evolving to meet any challenge and ultimately producing strains which demonstrate resistance to any particular therapy. It is inherent in the art of cancer treatment that the individual circumstances of a particular case must be taken into consideration when determining whether a particular treatment will be effective. The claimed invention concerns a method of treating every possible permutation of this complex phenomenon, regardless of the circumstances of each specific case. In the absence of clear, comprehensive data, it is assumed that a new therapy will be similar to the closest analogous art, (i.e. like chemotherapy, efficacious against some cancers under some circumstances rather than all cancers under all circumstances) and will not utterly transcend the limitations of the prior art merely by virtue of being new and different. The only difference pointed out by Applicant is that the claimed therapy is specifically targeted toward certain tumor-specific markers, which makes it more specific than current chemotherapeutic drugs which generally target all dividing cells. This is a **purely theoretical** consideration which, while it is expected to lead to a therapeutic benefit, cannot measure the full extent of that benefit. Merely being agnostic as to the efficacy against the full range of claimed subject matter does not render the claimed therapeutic method **more effective** than the current, well

characterized chemotherapeutic methods. While specific data do exist for this therapy, these data only concern the treatment of specific cancer xenografts under laboratory conditions, and are thus not representative of cancer as a whole. While clinical experience in naturally occurring human cancers is not required to enable specific embodiments of a therapeutic method, lack of such data weighs against the claim that the field is sufficiently well developed to make sweeping generalizations about the applicability of a therapy to all clinical cases.

In sum, Applicant's extraordinary claims lack the equally extraordinary evidence of a revolution in cancer therapy which would be required to enable the full scope of the claimed invention. Not every therapy that is different from the prior art is necessarily a significant improvement on the prior art. Thus Applicant's arguments are not found sufficient to overcome this rejection.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 149-167 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 89-107 of copending Application No. 11218044. This

is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Response to Argument: Applicant, in a response filed September 7, 2006, declined to address this provisional rejection until one set of claims is patented. It is noted that, although both sets of claims have since been amended, they are still identical. Thus the rejection is maintained.

The following new grounds of rejection are introduced:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 149-154, 156-176, and 180-192 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yan et al. (Reference cited in PTO-892) in view of Jamas et al. (US patent 5849720, cited in PTO-892) Yan et al. discloses a yeast-derived beta-glucan composition (denoted as SZP_g) capable of producing a synergistic complement-mediated antitumor effect in a mouse xenograft model of breast cancer (p. 304, right column) in combination with antitumor antibodies. (p. 3048, left column and figure 3) The beta-glucan has a 1,3-linked backbone and is branched with 1,6-linked side chains, (p. 3045, left column, first paragraph) and is obtained from yeast. (zymosan) The combination therapy led to a synergistic effect producing more than additive results in

the mice. It is explained that the normal antitumor effects of beta-glucans is only present in specific strains of mice having appropriate antibodies toward the tumor, and that the addition of exogenous antitumor antibodies can restore this activity in cases in which beta-glucan monotherapy is ineffective. (p. 3050, under the heading **Discussion**) Anti-GD2 antibodies are cites as a specific example. (p. 3050, right column, first paragraph) Yan et al. does not explicitly disclose a pharmaceutical composition comprising a beta-glucan and an antibody. Yan et al. does not disclose a composition in which the beta-glucan has the specific molecular weights of claim 158, the heat stability of claims 160-161, or the dosage of claim 162. Yan et al. also does not disclose that beta-glucan may be administered orally as in instant claim 168.

Jamas et al. discloses an orally available, immune-stimulating beta-glucan preparation, (column 4, lines 40-64) derived from yeast, bacteria, fungi, and plants. (column 1, lines 13-15) which has a molecular weight of 10000-500000 daltons, (column 4, lines 23-35) and is stable to heat treatment. (columns 5-6, examples 1-2) This beta-glucan has a 1,3-linked backbone and 1,6-linked branches, (column 4, lines 11-20) and is thus the same glucan described by Yan et al. The necessary dose varies on an individual basis. (column 4, lines 49-53)

It would have been obvious to one of ordinary skill in the art at the time of the invention to prepare a pharmaceutical composition comprising both a beta-glucan and an antibody as described in instant claim 149, and to use the beta-glucan of Jamas et al. in this composition having a molecular weight of 250-450 kD, or to provide the glucan independently for oral administration. One of ordinary skill in the art would have been

motivated to produce a pharmaceutical composition comprising a beta-glucan and an antibody because the method of Yan et al. comprises concurrently administering both of these active ingredients to a subject. One of ordinary skill in the art would have been motivated to use the composition of Jamas et al. because this composition contains a beta-glucan having the same 1,3 and 1,6-linkages described by Yan et al. One of ordinary skill in the art would have been motivated to formulate the beta-glucan separately for oral administration because the composition of Jamas et al. is capable of producing a systemic effect when administered orally. One of ordinary skill in the art would have been motivated to use a beta-glucan with a molecular weight of 250-450 kD because this range overlaps significantly with the range disclosed by Jamas et al. Note that the specific heat-stability described in instant claim 101 is an inherent property of the claimed invention and is thus present in the composition of Jamas et al. because the beta-glucan molecule in this composition is the same as that of the claimed invention. One of ordinary skill in the art would have been motivated to use the dose of beta-glucan disclosed in instant claim 162 because Jamas et al. discloses that the dose may be varied depending on the circumstances of each particular case. One of ordinary skill in the art would have reasonably expected success in producing an appropriate pharmaceutical composition and administering the claimed dose because the preparation of pharmaceutical composition comprising known active ingredients and the selection of specific dosages of known medications is part of the ordinary and routine level of skill in the art. One of ordinary skill in the art would reasonably have expected

success in using the composition of Jamas et al. because this composition comprises a beta-glucan which has the same backbone and linkages as that used by Yan et al.

Thus the invention taken as a whole is *prima facie* obvious.

Response to Argument: Applicant's arguments, filed September 7, 2006, with respect to the rejection of instant claims 149-154, 156-176, and 180-192 under 35 USC 103 as being unpatentable over the combination of Herlyn, Jamas et al., Yan et al., Marciani et al., Cheever et al., Chu et al., and Lane et al., for reasons of record stated in the office action filed March 10, 2006, have been fully considered but are moot in view of the new grounds of rejection set forth above.

Claims 155, 177, and 179 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yan et al. (Cited in PTO-892) in view of Jamas et al. (US patent 5849720, cited in PTO-892) as applied to claims 149-154, 156-176, and 180-192 above, and further in view of any one of Cheever et al., (US patent 6664370, cited in PTO-892) Onizuka et al., (Reference cited in PTO-892) Herrera et al., (Reference cited in PTO-892) or Rai et al. (Reference cited in PTO-892) The disclosure of Yan et al. in view of Jamas et al. is described above. Yan et al. in view of Jamas et al. does not explicitly disclose a method or composition involving an antibody that recognizes any of the antigens CD20, CD22, Her-2/neu, or CD25.

Cheever et al. discloses that the Her-2/neu antigen is an oncogene which is overexpressed in a variety of cancers including breast, ovarian, colon, lung, and prostate. (column 2, lines 1-21) Cheever et al. also discloses that the immune system

mounts an autochthonous immune response against HER-2/neu expressed by tumors which can be used to diagnose, monitor, and treat malignancies which overexpress this protein. (column 8, line 57 – column 9, line 15)

Onizuka et al. discloses a method of treating cancer by administering an anti-CD25 monoclonal antibody. (p. 3128, left column, bottom paragraph)

Herrera et al. discloses a method of treating cancer comprising administering anti-CD22 antibodies. (p. 853, left column, last paragraph)

Rai et al. discloses an anti-CD20 monoclonal antibody referred to as rituximab, which exerts cell- and compliment- mediated cytotoxicity against tumor cells *in vivo*. (p. 139, right column, last paragraph – p. 14, left column, first paragraph)

It would have been obvious to one of ordinary skill in the art at the time of the invention to use any of the monoclonal antibodies disclosed by Cheever et al., Onizuka et al., Herrera et al., or Rai et al. in the methods and compositions of Yan et al. in view of Jamas et al. One of ordinary skill in the art would have been motivated to use these antibodies because Yan et al. already discloses that beta-glucan produces a synergistic antitumor effect *in vivo* when combined with antitumor antibodies. One of ordinary skill in the art would have reasonably expected success because the disclosed antibodies have already been shown to be effective *in vivo*.

Thus the invention taken as a whole is *prima facie* obvious.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the

unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 168-192 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 89-107 of copending Application No. 11218044. (cited in PTO-892, herein referred to as '044) Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 89-107 of '044 anticipate instant claims 168-192. In particular these claims are drawn to a composition that is the same as the instant claims except that they further comprise an additional ingredient. Thus they fall completely within the instant claims 168-192 and anticipate these claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 168-188 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 10-13 of copending Application No. 10/565484 (Cited in PTO-892, herein referred to as '484) in view of any one of Onizuka et al., (Reference cited in PTO-892) Herrera et al., (Reference cited in PTO-892) Rai et al. (Reference cited in PTO-892) or Yue et al. (Reference included with PTO-892) Claim 10 of '484 discloses a composition comprising an effective amount of orally administered (1,3), (1,6) or (1,3),(1-4) beta-glucan capable of enhancing efficacy of IgM antibodies. Claims 11-13 disclose that the antibody being enhanced is an antibody against cancer or a tumor-binding antibody, which is capable of activating complement. Claims 10-13 of '484 are not drawn to a composition comprising this beta-glucan and additionally comprising an antibody..

The disclosures of any one of Onizuka et al., Herrera et al., Rai et al., and Yue et al. are discussed above.

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the composition of claims 10-13 of '484 with any of the antibodies disclosed by Onizuka et al., Herrera et al., Rai et al., or Yan et al. in order to treat cancer. One of ordinary skill in the art would have been motivated to use these antibodies because the aforementioned claims already state that the composition is capable of enhancing the effects of antitumor antibodies. One of ordinary skill in the art would have reasonably expected success because the disclosed antibodies have already been shown to be effective *in vivo*.

This is a provisional obviousness-type double patenting rejection.

Summary

No claims are allowed in this application.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric S. Olson whose telephone number is 571-272-9051. The examiner can normally be reached on Monday-Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on (571)272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Eric Olson
Patent Examiner
AU 1623
12/20/06

Anna Jiang
12/20/06
Supervisory Patent Examiner